

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 53110AWO	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/006685	International filing date (day/month/year) 19.06.2004	Priority date (day/month/year) 03.07.2003
International Patent Classification (IPC) or national classification and IPC C07C49/17, C07D417/06, C07D493/04		
Applicant SCHERING AKTIENGESELLSCHAFT		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table><tr><td><input checked="" type="checkbox"/></td><td>Box No. I</td><td>Basis of the report</td></tr><tr><td><input type="checkbox"/></td><td>Box No. II</td><td>Priority</td></tr><tr><td><input type="checkbox"/></td><td>Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input type="checkbox"/></td><td>Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VIII</td><td>Certain observations on the international application</td></tr></table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report																								
Name and mailing address of the IPEA/EP	Authorized officer																								
Facsimile No.	Telephone No.																								

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
 - ☐ international search (Rule 12.3 and 23.1(b))
 - ☐ publication of the international application (Rule 12.4)
 - ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
 - ☐ the international application as originally filed/furnished
 - ☒ the description:
 - pages 1-36 _____ as originally filed/furnished
 - pages* _____ received by this Authority on _____
 - pages* _____ received by this Authority on _____
 - ☒ the claims:
 - nos. 1-5 _____ as originally filed/furnished
 - nos.* _____ as amended (together with any statement) under Article 19
 - nos.* _____ received by this Authority on _____
 - nos.* _____ received by this Authority on _____
 - ☐ the drawings:
 - sheets _____ as originally filed/furnished
 - sheets* _____ received by this Authority on _____
 - sheets* _____ received by this Authority on _____
 - ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
 - ☐ the description, pages _____
 - ☐ the claims, nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages _____
 - ☐ the claims, nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	_____	YES
	Claims	1-5	NO
Inventive step (IS)	Claims	_____	YES
	Claims	1-5	NO
Industrial applicability (IA)	Claims	1-5	YES
	Claims	_____	NO
2. Citations and explanations (Rule 70.7)			
<p>The present application appears not to satisfy the requirements of PCT Article 33(2) because the subject matter of the claims is not novel. Claim 9 and pages 49-50 of the description of document D1 (WO 99/07692 A) concern, <i>inter alia</i>, a method for producing epothilone derivatives from the fragments $A+B = A-B$ and $A-B + C = A-B-C$, wherein all three fragments structurally overlap the A, B and C claimed in the present application. The formula AB in claim 9 of document D1 therefore appears to be prejudicial to the novelty of the present claim 5. The method of claim 9 of document D1 likewise appears to be prejudicial to the novelty of present claims 1-4. In particular, in the C fragment $U=C-R$ appears to overlap with G in document D1, and in fragment AB CH-CH versus D-E in AB of document D1 does not result in a new selection, since D-E form a unit, that is to say, they cannot be selected independently of each other. Consequently, this is considered no more than a selection from a list.</p> <p>Document D1 is the closest prior art. It discloses the production of epothilone derivatives from the fragments $A+B = A-B$ and $A-B + C = A-B-C$. The problem to be solved</p>			

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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by the present invention is understood to be that of providing an alternative method for producing epothilones. In the light of the experimental part it can be assumed that this problem is solved by the application. However, insofar as the subject matter of the present application can be considered novel, the fragments A, B and C are similar to those of document D1 to such an extent that the solution is obvious to a person skilled in the art. The problem to be solved by the present application must therefore be considered that of an alternative method having unexpected or surprising properties with respect to the closest prior art (D1). Without comparative test results or other arguments demonstrating the patentability of the invention it is not possible to assess whether the invention satisfies the requirements of PCT Article 33(3). The present application does not appear to meet the requirements of PCT Article 33(2) because the subject matter of the claims is not novel. Claim 9 and pages 49-50 of the description of document D1 (WO 99/07692 A) concern, *inter alia*, a method for producing epothilone derivatives from the fragments $A+B = A-B$ and $A-B + C = A-B-C$, wherein all three fragments structurally overlap with the fragments A, B and C claimed in the present application. The formula AB in claim 9 of document D1 therefore appears to be prejudicial to the novelty of the present claim 5. The method of claim 9 of document D1 likewise appears to be prejudicial to the novelty of the present claims 1-4. In particular, in the C fragment, $U=C-R$ appears to overlap with G in document D1, and in fragment AB, CH-CH as opposed to D-E in AB of document D1 does not lead to a novel selection, since D-E form a unit, that is to say,

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

they cannot be selected independently of each other.
Consequently, this is considered no more than a selection from a list.

Document D1 is the closest prior art. It discloses the production of epothilone derivatives from the fragments $A+B = A-B$ and $A-B + C = A-B-C$. The problem to be solved by the present invention is understood to be that of providing an alternative method for the production of epothilones. In the light of the experimental part, it can be assumed that this problem is solved in the application. However, insofar as the subject matter of the present application can be considered novel, the fragments A, B and C are similar to those of document D1 to such an extent that the solution is obvious to a person skilled in the art. The problem to be solved by the present application must therefore be considered that of making available an alternative method having unexpected or surprising properties with respect to the closest prior art document (D1). Without comparative test results or other arguments demonstrating the patentability of the invention it is not possible to assess whether the invention satisfies the requirements of PCT Article 33(3).